

Congress of the United States
Washington, DC 20515

January 17, 2003

The President
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Mr. President:

According to a recent *Washington Post* article, your administration has decided not to propose legislation to create a compensation program for first responders and health care workers who will be injured by the smallpox vaccine.¹ While noting your strong support for liability protection for vaccine manufacturers, hospitals and those administering the vaccine, this article quotes an administration advisor saying that the cost of compensating those injured by the vaccine is a “major stumbling block” for the creation of a compensation program.²

This position is manifestly unjust to health care workers and others who are preparing to risk being injured by the smallpox vaccine in order to protect the country in the event of a bioterrorist attack. Furthermore, this position threatens to undermine the smallpox immunization effort. Unless first responders and health care personnel can be assured that they will be compensated quickly and fairly, they may not be willing to assume the risk of vaccination. According to an Institute of Medicine’s report, released today, the lack of a compensation program “could seriously impact the program’s achievement of its overall goals of increasing United States terrorism preparedness.”³

We are writing to ask you to reverse your position and to work with Congress on the creation of a no-fault compensation program that can make sure that those who take the smallpox vaccine in order to ensure homeland security are adequately taken care of in the event they are harmed by this vaccine.

The homeland security bill that Congress passed at the end of last year provided extensive liability protection for makers of the smallpox vaccine, for health care facilities where the vaccine may be administered, and for health care professionals who may administer the

¹*Caregivers Protected Against Smallpox Lawsuits: Bush Plan Would Not Compensate Patients for Vaccine’s Side Effects or Accidental Exposure*, Washington Post (Jan. 14, 2003).

²*Id.*

³Institute of Medicine, *Review of the Centers for Disease Control and Prevention’s Smallpox Vaccination Program Implementation* (Jan. 16, 2003).

vaccine. These provisions not only failed to provide appropriate compensation for children and adults who might be injured by the smallpox vaccine, but actually took away existing legal rights to seek compensation.

According to the Centers for Disease Control and Prevention (CDC), and judging from prior experience with the vaccine, about one of every one million people vaccinated against smallpox will die, and several others will suffer serious medical complications, including brain damage, blindness, and significant scarring. Serious injury can occur even among unwitting people who have never been vaccinated but who catch the vaccine virus (called “vaccinia”) from individuals who were recently vaccinated.

Prior to the passage of the homeland security bill, individuals injured by the smallpox vaccine could bring actions in state court to recover damages under a variety of legal theories, such as product liability. Moreover, the federal government, if it wanted to provide protection to a vaccine manufacturer, could enter into an agreement to indemnify the manufacturer from liability. The indemnification approach would protect the manufacturer by ensuring that the government will reimburse it for any losses, but would not take away any legal rights of victims.

Under section 304 of the homeland security bill, however, all of the rights that persons injured by the smallpox vaccine currently have to seek compensation are eliminated. In place of the ability to bring product liability and other claims against vaccine manufacturers, health care facilities, or health professionals in state court, injured individuals are allowed to bring claims only against the federal government, in federal court, under the Federal Tort Claims Act and must prove negligence. These actions will be difficult to sustain because of the many restrictions on government liability under the Federal Tort Claims Act.

Section 304 even fails to assist persons who did not take the smallpox vaccine themselves, but are injured as a result of exposure to someone who did receive the vaccine. Small children are expected to be among those injured in this way.

By failing to put into place a compensation program for those injured by the vaccine, the homeland security bill also puts the success of any smallpox vaccination effort at risk. The Institute of Medicine correctly recommended that “informed consent forms include explicit notification of the availability, or lack thereof, of compensation for adverse reactions.”⁴ Under current law, such information would have to state that such compensation is not available. No doubt, some health care workers and first responders would decline to be vaccinated, knowing that a serious adverse reaction could lead them to lose their job and life savings without

⁴*Id.*

compensation. That is why the Institute of Medicine recommended that the CDC and the Department of Health and Human Services “support all efforts, some of which might be administratively or legislatively bold and creative, to bring this issue of compensation for smallpox vaccine adverse reactions — including those reactions that occur despite non-negligent manufacture and administration of the vaccine — to speedy resolution.”⁵

Administration officials have said that those injured by the smallpox vaccine would have to rely on workers’ compensation and health insurance to cover the costs of their injuries. However, these officials have conceded that some state compensation programs will not fully cover workers’ injuries,⁶ and workers’ compensation will not help someone who gets sick by coming into contact with someone who has recently been vaccinated. For those workers who do have health insurance, there is no guarantee that smallpox vaccine injuries will not be excluded from their coverage. Furthermore, it is possible that there will be people among the first wave of vaccinees who are uninsured or underinsured. It is also possible that someone who becomes ill through contact with a recently vaccinated person will be uninsured or will have insurance that does not cover smallpox vaccine injuries.

A far better approach than section 304 would be a no-fault compensation program modeled on the successful program we currently have for childhood vaccines. This approach would facilitate — not block — compensation, while at the same time it would also provide appropriate safeguards for vaccine manufacturers in order to assure a stable vaccine supply.

Members of Congress and congressional staff have repeatedly contacted the Department of Health and Human Services (HHS) over the past year to work together on a smallpox compensation program. On November 15, 2002, Rep. Waxman wrote a lengthy letter to Secretary Thompson asking about these provisions in the homeland security bill and the Administration’s plans to compensate those injured by the smallpox vaccine. Despite public assurance by an HHS official that HHS would be willing to work with Congress on compensation legislation, Secretary Thompson has not responded to this letter, and calls to HHS staff from congressional staff on this subject have not been returned. It is now quite clear that the Administration’s priority is only to protect the vaccine manufacturers, and to leave those injured by the vaccine to fend for themselves.

We urge you to reverse your position and follow the Institute of Medicine’s recommendations. We urge that you work with the Congress to provide a compensation program

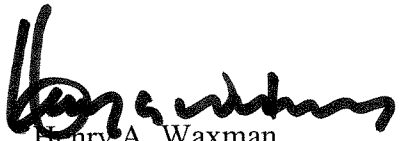
⁵*Id.*

⁶*Laws Protect Those With Smallpox Injuries*, Associated Press (Jan. 14, 2003).

President George W. Bush
January 17, 2003
Page 4

for those Americans — including an estimated 500,000 health care workers in the near term — who choose to risk their health to protect us all.

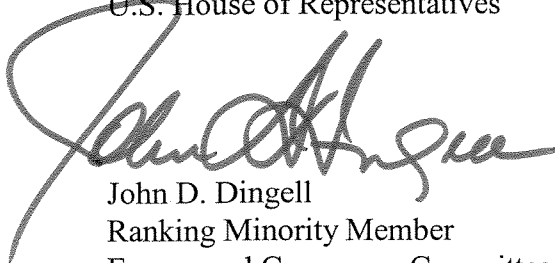
Sincerely,



Henry A. Waxman
Ranking Minority Member
Government Reform Committee
U.S. House of Representatives



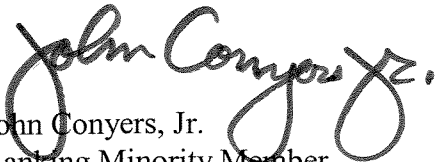
Nancy Pelosi
Democratic Leader
U.S. House of Representatives



John D. Dingell
Ranking Minority Member
Energy and Commerce Committee
U.S. House of Representatives



Sherrod Brown
Ranking Minority Member
Health Subcommittee
Energy and Commerce Committee
U.S. House of Representatives



John Conyers, Jr.
Ranking Minority Member
Judiciary Committee
U.S. House of Representatives



Edward J. Markey
Member
Energy and Commerce Committee
U.S. House of Representatives



Richard J. Durbin
Ranking Minority Member
Subcommittee on Oversight of
Government Management,
Restructuring, and the District
of Columbia
U.S. Senate



Hillary Rodham Clinton
Senator
U.S. Senate